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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,984	07/28/2003	Guohua Chen	ARC 3119 R1	7536

7590 09/17/2007

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,984	CHEN ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6,9-19,21-35,37-47 and 49-84* is/are pending in the application.

4a) Of the above claim(s) *21-27 and 49-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6,9-19,21-35,37-47 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4, 5, 7, 8, 20, 36 and 48 have been cancelled. Claims 21-27 and 49-83 have been withdrawn. Claims 2, 3, 6, 9-19, 28-35, 37-47 and 84 are under examination. Upon further consideration the Examiner has new ground of rejection. This action is non-final.

Comment: The relative terms "low", "medium" and "high" recited in claims 2 and 3, for example, are defined with specificity on page 23, [00079-00081].

Withdrawn rejections:

Applicant's amendments, filing of terminal disclaimers and arguments are sufficient to overcome the rejections of record and the Examiner hereby withdraws those rejections in favor of the rejection to follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 6, 9-19, 28-35, 37-47 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodbeck et al. (US 6,331,311), hereinafter '311, in view of Brodbeck et al. (6,130,200), hereinafter '200, and Penco et al. (Polymer International 1998, 46, 203-216).

Applicant claims an injectable gel composition comprising a plurality of bioerodible, biocompatible polymers, solvent and a beneficial agent.

Determination of the scope and content of the prior art

(MPEP 2141.01)

'311 teaches an injectable depot gel composition comprising a biocompatible polymer such as lactic acid based polymers with a number average molecular weight of from 1,000 to 120,000, an organic solvent and a beneficial agent dispersed in the gel (Abstract and claims 1-3 and 5). '311 teaches polylactides, polyglycolides, copolymers and mixtures thereof as the biocompatible polymer (claim 2). '311 teaches the solvent is present from 20 to 95 % by weight of the combined amounts of polymer and solvent (Claim 10). Therefore the polymer must be from 5 to 80 % by weight of the composition. '311 teaches benzyl benzoate, an aromatic ester, as a solvent (column 5, lines 8-15) and alcohols, polyols, esters, carboxylic acids, ketones, aldehydes and mixtures thereof as emulsifying agents (claims 19). '311 teaches prolonged release of the beneficial agent up to 90 days and modifying the release by adjusting the amounts of components for any given polymer and any given solvent (column 7, line 35 bridging column 8, line 53). '311 teaches a kit for the injectable depot composition with the components (a) a biocompatible polymer and organic solvent; (b) emulsifying agent and (c) the beneficial agent

(claim 27). The beneficial agent is thus separated from the solvent and mixed before use (column 8, lines 53-61). (Note: components (d)-(g) are optional in instant claim 84).

'200 teaches a gel composition for implantation of a beneficial agent to a subject comprising a biocompatible polymer, a biocompatible solvent with low water miscibility that forms a gel with the polymer and a beneficial agent (Abstract). '200 teaches poly(lactide-co-glycolide) copolymer, benzyl benzoate and a beneficial agent (Claims 1-3) wherein the copolymer has a number average molecular weight of from 1,000 to 120,000 (claim 15). A component solvent can be added such as diethyl phthalate (claim 17). '200 teaches that useful solvents are less than 7% water soluble by weight (column 12, lines 12-65). '200 teaches the use of RESOMER® RG502 AND RESOMER® RG503 for use in the invention (column 24, line 46 bridging column 25, line 5).

Penco et al. teach benzyl alcohol as a known solvent for PLGA (page 204-205, 2. synthesis).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1.The difference between the instant invention and '311 is that '311 does not expressly teach mixtures of high, medium and low molecular weight lactic acid based polymers in the injectable drug depot. This deficiency is cured by the teachings of '200.

2. The difference between the instant invention and '311 is that '311 does not expressly teach benzyl alcohol as a solvent. This deficiency in '311 is cured by the teachings of Penco et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a mixture of high, medium and low biocompatible lactic acid based polymers as taught by '311 and use for example the lactic acid based polymers RESOMER® RG502 AND RESOMER® RG503, as suggested by '200, in the gel depot of '311 and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because '311 teaches one of ordinary skill in the art mixtures of polylactides and copolymers thereof and teaches a wide range of molecular weights that encompass the instantly claimed high, medium and low molecular weight ranges that can be used to make the injectable drug depot gel composition. It is then merely routine optimization and judicious selection of known components in the art, for example RESOMER® RG502 AND RESOMER® RG503, for use in the composition especially when '200 teaches use of these materials for the same purpose. With respect to the limitation of systemic delivery of the beneficial agent over a duration of one year or local delivery of the beneficial agent over a duration of up to one year, that is merely routine optimization, as taught by '311, of the components to arrive at that desired release profile.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use benzyl alcohol, as taught by Penco et al., as the solvent in the composition of '311 and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because benzyl alcohol is a known solvent for PLGA polymers as taught by Penco et al. Benzyl alcohol

intrinsically has the properties of water miscibility instantly claimed in the absence of evidence to the contrary (see instant claims 12-15 and 40-43).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary: The instantly claimed components for the injectable depot are known components. PLGA polymers of various molecular weights are known in the art of gel drug delivery vehicle formulation. The art teaches mixtures of the polymers for making injectable gel drug depots. Solvents for the PLGA polymers with less than 7% miscibility with water are known in the art. One of ordinary skill in the art would expect to make an injectable drug depot from mixing the polymers of different molecular weights in the solvent and adding a beneficial agent. The instant invention appears to be ordinary innovation of what is taught in the prior art. From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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